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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,789	10/27/2000	Michael Spencer	DEKM:157USC1	7335

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/698,789

Applicant(s)

SPENCER ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 84-87 and 96-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84-87 and 96-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) -
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) -
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825. See page 86, lines 20 and 21; page 87, lines 2 and 3; page 97, line 2. If the disclosed nucleotide sequences are in the Sequence Listing, then the specification must be amended to include the SEQ ID NO. If the disclosed nucleotide sequences are not in the Sequence Listing, then Applicant must submit a new, revised paper copy of the Sequence Listing accompanied by a Computer Readable Form of the sequence listing and the proper statement regarding its content must be submitted in response to this Office action. Applicant should include a response to the Sequence Rules in addition to the other issued in this Office Action, failure to respond to the Sequence Rules will be held to be non-responsive to this Office Action.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR §§ 1.78(a)(2) and (a)(5)). Specifically, the statement on the first line of the Specification should be amended to designate the status of the parent applications.

Information Disclosure Statement

3. The information disclosure statement filed 26 March 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically the PCT Search Report for PCT/US98/06640 was not found in the parent applications and was not submitted in the instant application. If Applicant wishes this reference to be considered, a copy of the reference should be submitted in response to this Office action.

Drawings

4. The drawings in this application are objected to by the Draftsperson. See the attached PTO-948 form. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Status of the Application

5. Claims 1-82, 88-95 and 100-118 have been cancelled as requested in the Request for Filing, filed on 27 October 2000. Claims 83-87 and 96-98 have been amended as requested in the Preliminary Amendment filed on 27 October 2000.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 83-87 and 96-99 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a method of plant breeding comprising a first parent maize plant comprising a first EPSPS transgene, wherein said first plant is capable of being rendered male-sterile by treatment of said plant with glyphosate.

Applicant describes maize lines GG25 and GJ11, comprising an EPSPS transgene that are capable of being rendered male-sterile by treatment of said maize lines with glyphosate.

Applicant does not describe any other maize line comprising an EPSPS transgene that is capable of being rendered male-sterile by treatment of said maize line with glyphosate.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description

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purposes, even when accompanied by a method of obtaining the claimed sequence. In the instant case, Applicant's belief of function as directed to transforming maize plants using specific promoters that allow for rendering maize plants male sterile does not sufficiently describe the instant invention, because the description is only based to function, and does not correlate structure and function.

8. Claims 83-87 and 96-99 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of plant breeding comprising Applicant's maize line GG25, deposited at the ATCC under Accession No. 209033 or maize line GJ11, deposited at the ATCC under Accession No. 209030, does not reasonably provide enablement for a method of plant breeding using any other maize plant comprising an EPSPS transgene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a method of plant breeding comprising a first parent maize plant comprising a first EPSPS transgene, wherein said first plant is capable of being rendered male-sterile by treatment of said plant with glyphosate.

Applicant teaches maize lines GG25 and GJ11, comprising an EPSPS transgene that are capable of being rendered male-sterile by treatment of said maize lines with glyphosate.

Applicant does not teach any other maize line comprising an EPSPS transgene that is capable of being rendered male-sterile by treatment of said maize line with glyphosate.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance for producing a maize plant comprising an EPSPS transgene that is capable of being rendered male-sterile by treatment of said maize plant with glyphosate. Applicant states on page 78, lines 26-29, that Applicant believes that the glyphosate inducible nature of male-sterility in plants having the GG25 and GJ11 transformation events is a result of promoter function in expression of the resistance protein, in this case a mutant EPSPS. Conversely, Applicant provides no evidence that the choice of promoter sequence is in fact what has rendered said transformation events capable of being rendered male sterile by application of glyphosate. The nature of the claimed method is such that it requires that the first parental maize plant to be capable of being rendered male sterile by the application of glyphosate. The prior art teaches that glyphosate can be used to render plants male sterile but retain female fertility (see Dhingra *et al* 1988, U.S. Patent 4,735,649). The art also teaches that maize lines are variable in the response of their pollen to glyphosate, and tolerance or susceptibility is not an inherent property of maize pollen, but dependent upon the genetic background of the maize line (see Frascaroli *et al* 1992, J.

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Genet. & Breed. 46:49-56, especially the Abstract on page 49). In addition, the art teaches that integration of transgenes is essentially random in the genome and variability is often observed from one transgenic plant to another ascribed to 'position effect variation' (see Hansen *et al* 1999, Trends in Plant Science 4(6):226-231, see especially page 230, left column, last two paragraphs). Thus, it is unclear from the instant specification if the EPSPS transgene of maize lines GG25 and GJ11 produces the desired, conditional phenotype because of genotypic variation or because of a position effect variation due to where the transgene has been inserted into the genome of the specific maize lines. Hence, given the limited guidance by Applicant, the nature of the claimed invention and the teaching of the art it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to transform a myriad of maize plant with an EPSPS transgene, using a myriad of promoters and screen through a myriad of transgenic maize lines to identify those maize lines that could be rendered male sterile by applying glyphosate as broadly claimed.

If Applicant is able to successfully argue the instant rejection as directed to specific maize lines, then the instant claims would be rejected as only enable for a method comprising a maize plant transformed with an EPSPS encoding polynucleotide operably linked to a polynucleotide encoding a maize histone promoter or a CaMV35S-*Arabidopsis* histone promoter. Substantial evidence would be required for the use of other promoters that could be used in the claimed method within the scope of the claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 83-87 and 96-99 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fabijanski *et al* (U.S. Patent 5,356,799, published 18 October 1994) in view of Dhingra *et al* (U.S. Patent 4,735,649, published 5 April 1988)

Fabijanski teaches a method of plant breeding comprising transforming a plant with a gene for glyphosate resistance, such as the EPSPS gene, and using said transformed plant in a method of plant breeding wherein glyphosate is used to produce male sterility in the female parent plant (see column 5, lines 44-59).

Fabijanski does not specifically teach the use of glyphosate to produce male sterility.

Dhingra teaches a method of producing male sterile plants using glyphosate in a process of breeding (see claims 1 and 2).

The instant claims are *prima facie* obvious because it is unclear of the exact nature of the conditional tolerance to glyphosate of Applicant's maize lines GG25 and GJ11. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to practice the method of Fabijanski in view of the teachings of Dhingra. Given the success of Dhingra in using glyphosate to produce

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male sterility in plants in a process of breeding, one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success in using the teachings of Fabijanski to use a resistant male parent comprising an EPSPS transgene and a non-resistant female parent to practice the method of plant breeding. If Applicant's maize lines GG25 and GJ11 are conditionally capable of being rendered male sterile by glyphosate due to genetic variation or a positional effect of the transgene, the said maze lines would have been functionally and reproductively identical to those suggested by Fabijanski. Those limitations at claims 96-99 would have been considered obvious experimental variations to one of ordinary skill in the art for the specific plant used, such as maize, and variety of said plant used.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983), which teach that the evidence of non-obviousness should be commensurate with the scope of the claims.

Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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David H. Kruse, Ph.D.
30 September 2002